

Appl. No. To be assigned  
Amdt dated February 11, 2005

200.1156US

## I. AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

### Listing of Claims

Claim 1 (Original) A pharmaceutical formulation comprising:  
a substrate comprising an opioid antagonist;  
a diffusion barrier coating comprising an anionic polymer coated over said  
substrate; and  
a coating comprising a hydrophobic material coated over said diffusion barrier  
coating.

Claim 2 (Original) The pharmaceutical formulation of claim 1, wherein the substrate comprises  
opioid antagonist coated over a core.

Claim 3 (Original) The pharmaceutical formulation of claim 2, wherein the core is a  
pharmaceutically acceptable inert bead.

Claim 4 (Original) The pharmaceutical formulation of claim 1, wherein the antagonist is  
dispersed in matrix multiparticulates.

Claim 5 (Original) The pharmaceutical formulation of claim 1, wherein the opioid antagonist is  
protonated.

Claim 6 (Original) The pharmaceutical formulation of claim 5, wherein the protonated opioid  
antagonist has affinity for the anionic polymer.

Claim 7 (Original) The pharmaceutical formulation of claim 1, wherein the anionic polymer is selected from the group consisting of an acrylic polymer, acrylic copolymer, methacrylic polymer, methacrylic copolymer, and mixtures thereof.

Claim 8 (Original) The pharmaceutical formulation of claim 1, wherein the anionic polymer is a non-acrylic enteric coating material.

Claim 9 (Original) The pharmaceutical formulation of claim 8, wherein the enteric coating material is selected from the group consisting of cellulose acetate phthalate, hydroxypropyl methylcellulose phthalate, carboxymethyl ethylcellulose, hydroxypropyl methylcellulose acetate succinate, polyvinyl acetate phthalate, cellulose acetate trimellatace, cellulose acetophthalate, cellulose acetate terephthalate, polyvinyl alcohol phthalate, and mixtures thereof.

Claim 10 (Original) The pharmaceutical formulation of claim 1, wherein the diffusion barrier coating is in an amount from about 0.1 to about 10 percent by weight of the substrate.

Claim 11 (Original) The pharmaceutical formulation of claim 1, wherein the opioid antagonist is in a therapeutically effective amount.

Claim 12 (Original) The pharmaceutical formulation of claim 1, comprising a plurality of said substrates.

Claim 13 (Amended) The pharmaceutical formulation of claim 12, wherein said plurality of said substrates comprises a therapeutically effective amount of said the opioid antagonist.

Claim 14 (Original) The pharmaceutical formulation of claim 1, wherein the coating comprising the hydrophobic material provides for the controlled release of the opioid antagonist.

Claim 15 (Original) The pharmaceutical formulation of claim 1, wherein the coating comprising the hydrophobic material provides for the sequestration of the opioid antagonist.

Claim 16 (Original) The pharmaceutical formulation of claim 1, wherein the hydrophobic material is selected from the group consisting of a cellulosic material, a cellulosic polymer, an acrylic polymer or copolymer, a methacrylic polymer or copolymer, and mixtures thereof.

Claim 17 (Original) The pharmaceutical formulation of claim 1 wherein said opioid antagonist is selected from the group consisting of naltrexone, naloxone and pharmaceutically acceptable salts thereof.

Claim 18 (Original) A pharmaceutical formulation comprising:  
a substrate comprising an opioid analgesic,  
a diffusion barrier coating comprising an anionic polymer coated over said substrate,  
and  
a coating comprising a hydrophobic material coated over said diffusion barrier coating;  
said hydrophobic material providing for the controlled release of the opioid analgesic.

Claim 19 (Original) The pharmaceutical formulation of claim 18, wherein the substrate comprises the opioid analgesic coated over a core.

Claim 20 (Original) The pharmaceutical formulation of claim 19, wherein the core is a pharmaceutically acceptable bead.

Claim 21 (Original) The pharmaceutical formulation of claim 18, wherein the opioid analgesic is dispersed in matrix multiparticulates.

Claim 22 (Original) The pharmaceutical formulation of claim 18, wherein the opioid analgesic is protonated.

Claim 23 (Original) The pharmaceutical formulation of claim 22, wherein the protonated opioid analgesic has affinity for the anionic polymer.

Claim 24 (Original) The pharmaceutical formulation of claim 18, wherein the anionic polymer is selected from the group consisting of an acrylic polymer, arylic copolymer, methacrylic polymer, methacrylic copolymer, and mixtures thereof.

Claim 25 (Original) The pharmaceutical formulation of claim 18, wherein the anionic polymer is a non-acrylic enteric coating material.

Claims 26 -27 (Cancelled)

Claim 28 (Original) The pharmaceutical formulation of claim 25, wherein the enteric coating material is selected from the group consisting of cellulose acetate phthalate, hydroxyhydroxypropyl methylcellulose phthalate, carboxymethyl ethylcellulose, hydroxypropyl methylcellulose acetate succinate, polyvinyl acetate phthalate, cellulose acetate trimellataate, cellulose acetophthalate, cellulose acetate terephthalate, polyvinyl alcohol phthalate, and mixtures thereof.

Claim 29 (Original) The pharmaceutical formulation of claim 18, wherein the diffusion barrier coating is in an amount of from about 0.1 to about 10 percent by weight of the substrate.

Claim 30 (Original) The pharmaceutical formulation of claim 18, wherein the opioid analgesic is in a therapeutically effective amount.

Claim 31 (Original) The pharmaceutical formulation of claim 18, comprising a plurality of said substrates.

Claim 32 (Original) The pharmaceutical formulation of claim 31, wherein said plurality of said substrates comprises a therapeutically effective amount of said opioid analgesic.

Claim 33 (Original) The pharmaceutical formulation of claim 18, wherein the hydrophobic material is selected from the group consisting of a cellulosic material, a cellulosic polymer, an acrylic polymer or copolymer, a methacrylic polymer or copolymer, and mixtures thereof.

Claim 34 (Original) The pharmaceutical formulation of claim 18, wherein said opioid analgesic is selected from the group consisting of anileridine, buprenorphine, codeine, fentanyl, hydrocodone, hydromorphone, levorphanol, morphine, meperidine, oxycodone, oxymorphone, tramadol, salts thereof, and mixtures thereof.

Claim 35 (Original) A process for preparing a pharmaceutical formulation comprising:  
a) forming a substrate comprising an opioid antagonist;  
b) applying a diffusion barrier coating comprising an anionic polymer onto said substrate; and  
c) applying a coating comprising a hydrophobic material over said diffusion barrier coating.

Claim 36 – 49 (Cancelled)

Claim 50 (Original) A process for preparing a pharmaceutical formulation comprising:  
a) forming a substrate comprising an opioid analgesic;  
b) applying a diffusion barrier coating comprising an anionic polymer onto said substrate; and  
c) applying a coating comprising a hydrophobic material over said diffusion barrier coating said coating providing for the controlled release of the opioid analgesic.

Claim 51 (Original) The process of claim 50, wherein said opioid analgesic is selected from the group consisting of anileridine, buprenorphine, codeine, fentanyl, hydrocodone, hydromorphone, levorphanol, morphine, meperidine, oxycodone, oxymorphone, tramadol, salts thereof and mixtures thereof.

Claim 52 (Original) A method of treating pain in a patient in need of said treatment comprising administering the formulation of claim 18 to said patient.